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United States General Accounting Office

1
Briefing Report to the Chairman
Subcommittee on Human Resources and
Intergovernmental Relations
Committee on Government Operations
House of Representatives

September 1990

AGENT ORANGE STUDIES

Pool Contracting
Practices at Centers
for Disease Control
Increased Costs

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General Government Division

B-240921

September 28, 1990

The Honorable Ted Weiss
Chairman, Subcommittee on Human
Resources and Intergovernmental Relations
Committee on Government Operations
House of Representatives

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Dear Mr. Chairman:

This briefing report responds to your request and addresses the efforts of the Department of Health and Human Services' (HHS) Centers for Disease Control (CDC) to study the effects of Agent Orange on the health of Vietnam veterans. Specifically, we determined how CDC used \$70.4 million it received from the Department of Veterans Affairs (VA) to do the studies. We also examined CDC's contracting and contract administration practices on contracts it awarded for the studies.

On September 11, 1990, we briefed the Subcommittee on the results of our work. As agreed with the Subcommittee, the information presented at the briefing is summarized in this letter and detailed in appendix I.



Background

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United States military forces sprayed about 20 million gallons of herbicides in Vietnam during the Vietnam conflict. The spraying was done to destroy crops, to clear vegetation, and to cause trees and plants to lose their leaves. United States ground troops came in contact with these herbicides when they patrolled the sprayed areas. Fifteen different herbicides were used, including over 11 million gallons of an herbicide called Agent Orange. Started in 1962, the spraying reached a high point in 1967 and declined rapidly in 1970 after it was reported that mice exposed to herbicide components bore offspring with birth defects. The spraying was discontinued in 1971.

In December 1979, Congress passed Public Law 96-151, which directed VA to do a study to assess any long-term health effects on Vietnam veterans caused by exposure to dioxin, a component of Agent Orange. The law required the Office of Technology Assessment (OTA) to approve the study design, called a protocol, and to monitor the study to ensure compliance with the approved protocol. JPK

In November 1981, Congress amended Public Law 96-151 to expand the study's scope to include Vietnam veterans' exposure to other potentially

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health-degrading substances or conditions, including other types of herbicides, chemicals, and medications.

When VA failed to develop a protocol acceptable to OTA, Congress urged VA to transfer the study to CDC. In January 1983, VA and CDC signed an interagency agreement that transferred funds, personnel positions, prior work, and authority to do the study from VA to CDC.

CDC planned the following three major studies to satisfy the legislative requirements:

- a Vietnam Experience Study to determine the long-term health effects of military service in Vietnam,
- an Agent Orange Study to determine if there is a statistically significant relationship between exposure to Agent Orange and veterans' health, and
- a Selected Cancers Study to determine if there is a higher incidence of selected rare types of cancer among Vietnam veterans than in a control group of Americans selected at random.

The Vietnam Experience Study and the Agent Orange Study were to be done sequentially beginning with the Vietnam Experience Study. These two studies were to be done using the same two major contracts—a contract for interviews of veterans to obtain information on their health and a contract for medical and psychological examinations of veterans to evaluate their health. The Selected Cancers Study was planned to run concurrently with, but separate from, the two other studies. Work on the Selected Cancers Study was done under 13 major contracts.

When CDC found that using military personnel records did not accurately identify the exposure of veterans to Agent Orange, it added a fourth study, the Agent Orange Validation Study. This study was done to determine if military personnel records could be used to accurately identify veterans who had been exposed to high levels of dioxin.

Results in Brief

VA transferred \$70.4 million of its appropriated funds to CDC. Between October 1982 and March 1990, CDC spent \$51.5 million on contracts, personnel, equipment, and related items. In 1989, CDC returned \$14.3 million to the Treasury and, as directed by legislation, transferred \$3 million to the Air Force and \$1 million to VA in 1988 for studies on the spraying of herbicides in Vietnam. As of March 31, 1990, CDC had \$561,995 remaining to complete its planned work.

CDC awarded the two major contracts for interviews and examinations on the Vietnam Experience and Agent Orange Studies before it had developed an approved protocol to accurately identify Agent Orange exposure using military personnel records. When the contractors completed work on the Vietnam Experience Study in 1986, CDC did not have a methodology to accurately identify Agent Orange exposure. As a result, CDC was unable to have the contractors start work on the Agent Orange Study and paid the contractors \$6.6 million, or about 20 percent of the money it spent on contracts, for down-time it caused the contractors and for work that was not needed to do the studies. We also found examples of poor contract negotiating and contract administration that increased contract costs by \$86,779.

CDC completed and issued reports on the Vietnam Experience Study in 1988 and the Selected Cancers Study in 1990. However, CDC cancelled the Agent Orange Study in October 1987 after it concluded, on the basis of its findings from the Agent Orange Validation Study, that military records could not be used to accurately determine the exposure of veterans to Agent Orange.

Approach

Our objectives were to (1) determine the amount of funds CDC received to do the studies, (2) determine how CDC used the funds it received for the studies, and (3) evaluate the contracts awarded for the studies to identify weaknesses that may have occurred in CDC's contracting or contract administration practices.

We examined CDC's accounting records, contract files, and CDC's payments to contractors. We also interviewed CDC and contractor officials who managed CDC's studies. Further details on our objectives, scope, and methodology are discussed in appendix II.

As requested by the Subcommittee, we did not obtain official comments from the agency on this briefing report; however, we obtained the views of agency officials. CDC officials said that in their view the contracts awarded and the payments made on them were proper. They pointed out that (1) the contracts' success was dependent on procedures and methods that were untested and (2) they knew a decision not to proceed with the Agent Orange Study might be necessary. Their specific comments on the matters discussed in the report are presented in appendix I.

As arranged with the Subcommittee, unless you publicly announce its contents earlier, we plan no further distribution of this briefing report until 30 days from the date of this letter. At that time we will send copies to the House and Senate Committees on Veterans Affairs, House and Senate Committees on Appropriations, Senate Committee on Governmental Affairs, House Committee on Government Operations, Department of Health and Human Services, Department of Veterans Affairs, Office of Management and Budget, and other interested parties. Copies will be made available to others upon request.

Major contributors to this report are listed in appendix III. If you have any questions regarding this report, please call me on 275-8676.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "L. Nye Stevens". The signature is fluid and cursive, with the first name "L." and last name "Stevens" clearly legible.

L. Nye Stevens
Director, Government Business
Operations Issues

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Abbreviations

CDC	Centers for Disease Control
HHS	Department of Health and Human Services
OTA	Office of Technology Assessment
RTI	Research Triangle Institute
VA	Department of Veterans Affairs

CDC's Contracting for Agent Orange Studies

GAO Background

P.L. 96-151 authorized an Agent Orange Study.

P.L. 97-72 expanded the scope of the study.

Interagency agreement transferred authority for study from VA to CDC.

Background

The responsibility for the Agent Orange studies is outlined in two public laws and an interagency agreement between VA and CDC.

Public Law 96-151 Authorized an Agent Orange Study

Public Law 96-151, enacted in December 1979, required VA to design and do a study of Vietnam veterans who, while serving in Vietnam, were exposed to dioxin, a chemical component produced during the manufacture of various herbicides, including Agent Orange. The purpose of the study was to determine if exposure to the dioxin caused any adverse long-term health effects. The law required the Office of Technology Assessment (OTA) to approve the study design, referred to as a protocol,

and to monitor the performance of the study to ensure compliance with the approved protocol.

**Public Law 97-72
Expanded the Scope of the
Study**

Public Law 97-72, signed in November 1981, amended Public Law 96-151 and authorized VA to expand the scope of the original study. The purpose of the expansion was to allow an evaluation of any long-term adverse health effects on veterans resulting from other Vietnam service factors, including other herbicides, chemicals, medications, or environmental hazards or conditions.

**Interagency Agreement
Transferred Authority for
Study From VA to CDC**

VA spent nearly 3 years attempting to develop an acceptable protocol for the Agent Orange Study, without success. One of the reasons VA was unable to develop a protocol was the difficulty it encountered in determining which veterans were likely to have been exposed and which veterans were not likely to have been exposed to Agent Orange. Because of VA's failure to develop an acceptable protocol, Congress urged VA to transfer the study to CDC. In January 1983, VA signed an interagency agreement with CDC to transfer to CDC the personnel positions, funds, and authority for the design, implementation, analysis, and scientific interpretation of the studies directed by Public Laws 96-151 and 97-72.

GAO CDC's Proposed Agent Orange Studies

Vietnam Experience Study

Agent Orange Study

Selected Cancers Study

Agent Orange Validation Study

CDC's Proposed Agent Orange Studies

CDC originally planned three studies to satisfy the requirements of Public Laws 96-151 and 97-72. These were a Vietnam Experience Study, Agent Orange Study, and Selected Cancers Study. A fourth study, the Agent Orange Validation Study, was added to determine if military records could accurately identify veterans' exposure to Agent Orange.

Vietnam Experience Study

The Vietnam Experience Study addressed the long-term health effects of military service in Vietnam. The study design included a comparison of the current health status of 12,000 veterans—6,000 Vietnam veterans and 6,000 non-Vietnam veterans.

The study had three major parts, including (1) mortality assessments to determine which veterans had died since they were discharged from the military and the cause of their deaths, (2) health interviews, and (3) comprehensive medical and psychological examinations. The medical and psychological examinations were to be given to 4,000 Veterans, including 2,000 Vietnam and 2,000 non-Vietnam veterans.

The study was completed and reports were issued during 1987 and 1988. CDC reported that the Vietnam Experience Study showed that there was no significant difference between the health of Vietnam and non-Vietnam veterans.

Agent Orange Study

In the Agent Orange Study, CDC planned to look at the long-term health effects of exposure to dioxin in herbicides used in Vietnam. The study design included a comparison of the health status of 18,000 Vietnam veterans placed in three groups. These groups included 6,000 veterans who served in areas of Vietnam where herbicides were used and who were likely to have been exposed, 6,000 veterans who served in areas of Vietnam where herbicides were used but who were not likely to have been exposed, and 6,000 veterans who served in areas of Vietnam where herbicides were not used.

The study was to have the same three major parts as the Vietnam Experience Study, with medical and psychological examinations given to 6,000 of the 18,000 veterans, including 2,000 veterans from each of the three study groups.

CDC did not do the study because it concluded that the military records it planned to use on the study could not accurately identify combat veterans who were exposed to Agent Orange.

Selected Cancers Study

The Selected Cancers Study was done to determine if Vietnam veterans have an increased risk of developing six types of rare cancers that were believed to have been associated with exposure to herbicides with dioxin. These cancers included non-Hodgkin's lymphoma, soft tissue and other sarcomas, Hodgkin's disease, nasal cancer, nasopharyngeal cancer, and primary liver cancer.

The study included two groups: a cancer-case and a control group. Participation in both groups was restricted to men who were between 15 to 39 years old in 1968, the peak of United States troop strength in

Vietnam. To be eligible for the study, cancer-case group members had to be diagnosed with one of the six cancers between late 1984 and late 1988 and live in a geographical area covered by the tumor registries used in the study. These areas included the states of Connecticut, Kansas, and Iowa and the metropolitan areas of Miami, Detroit, San Francisco, Seattle, and Atlanta. The control group was comprised of men who did not have any of the six cancers and who were scientifically selected from households with telephones. Information on military service in Vietnam, along with relevant and occupational history, was collected from both cancer-case and control groups. CDC then determined the relationship of the rates of cancer to service in Vietnam.

The study was completed and the results published in March 1990. CDC reported that Vietnam veterans had a significantly higher risk than the general public of contracting one of the six cancers, non-Hodgkin's lymphoma. Additionally, CDC reported that Vietnam veterans did not have a significantly higher risk than the general public of contracting any of the remaining five cancers.

Agent Orange Validation Study

CDC did the Agent Orange Validation Study in 1987 to determine whether military records could be used to accurately establish Vietnam veterans' exposure to dioxin. The study was designed to test dioxin levels in the blood of Vietnam veterans who, on the basis of interpretation of the military records, were believed to have been exposed to Agent Orange in varying degrees and veterans who did not serve in Vietnam. CDC believed that a high level of dioxin in the blood of the Vietnam veterans would indicate that military records could be used to determine exposure to Agent Orange. Blood tests were given to 768 veterans, including 665 Vietnam veterans and 103 non-Vietnam veterans. Eight veterans were unable to give a sufficient amount of blood for the blood test.

The study was completed in September 1987, and CDC reported that it found no significant difference in the dioxin level between the blood of Vietnam and non-Vietnam veterans. Because of these results, CDC concluded that military records could not be used to accurately identify enough Vietnam veterans who had been exposed to Agent Orange to do a scientifically valid Agent Orange Study. Therefore, it cancelled the Agent Orange Study in October 1987.

GAO Source, Use, and Transfer
of Unused Funds

	(millions)
Received from VA	\$ 70.4
Spent by CDC	\$ 51.5
Retained to finish work	\$ 00.6
Unused funds transferred to	
•U. S. Treasury	\$ 14.3
•Air Force	\$ 03.0
•VA	\$ 01.0

Source, Use, and
Transfer of Unused
Funds

CDC received its Agent Orange funds from appropriations requested by VA. CDC spent funds studying the health of Vietnam veterans and transferred most of the unused funds to the Treasury, Air Force, and VA. As of March 30, 1990, CDC had retained \$561,995 to complete work on its projects and to close out the Selected Cancers Study contracts.

**Agent Orange Funds
Provided to CDC**

In accordance with the interagency agreement signed by VA and CDC, VA requested appropriations for CDC's Agent Orange studies and transferred funds to CDC. VA transferred a total of \$70.4 million to CDC to do its studies. These transfers included

- \$2.1 million in fiscal year 1983 appropriations,
- \$54.0 million appropriated by Public Law 98-181, and
- \$14.3 million in additional appropriations through fiscal year 1989.

**Funds Spent by CDC and
Remaining to Complete
Work**

As of March 30, 1990, CDC had spent \$51.5 million on contracts, personnel costs, equipment, supplies and materials, and various related costs. CDC had \$561,995 on hand to complete its studies.

Transfer of Unused Funds

CDC transferred \$18.3 million of unused funds to the Treasury, Air Force, and VA. This included

- \$14.3 million that was returned to the Treasury on September 11, 1989;
- \$3 million to the Air Force in 1988, which was required by Public Law 100-687, for blood tests on Air Force veterans who were directly involved with the spraying of Agent Orange in Vietnam; and
- \$1 million to VA for a contract in 1988, which was required by Public Law 100-687, to study the scientific evidence of health effects caused by exposure to toxic chemicals contained in herbicides used in Vietnam.

GAO How CDC Spent Funds

	(millions)
Contracts	\$ 33.2
Personnel	\$ 15.0
Equipment	\$ 02.2
Miscellaneous	\$ 01.1
Total	\$ 51.5

How CDC Spent Funds

CDC spent funds it received from VA on contracts, personnel costs, equipment, and miscellaneous expenses.

Contracts

CDC used \$33.2 million for contracts and interagency agreements to do the four studies. This included about \$31.9 million for 15 major contracts and about \$1.1 million for several other smaller contracts and assistance provided by other federal agencies.

Vietnam Experience, Agent Orange, and Agent Orange Validation Studies

CDC spent \$25.6 million on the two major contracts for the Vietnam Experience Study, Agent Orange Study, and Agent Orange Validation Study. These contracts were for interviews and examinations of veterans and were awarded to Research Triangle Institute (RTI) and Lovelace Medical Foundation.

RTI was awarded a \$7.5 million contract on August 1, 1984, to interview between 30,000 and 36,488 Vietnam veterans for the Vietnam Experience and Agent Orange Studies. Under the contract terms, CDC was to select the names of veterans from military records and provide the names to RTI. RTI's employees were to interview the veterans to obtain information about the veterans' military service, medical histories, and current health.

RTI completed 16,529 interviews, including 15,677 Vietnam Experience Study interviews and 852 Agent Orange Validation Study interviews, for which it was paid \$4.4 million. No interviews were done on the Agent Orange Study because it was cancelled.

Lovelace Medical Foundation was awarded a \$35.9 million contract on November 29, 1984, to do about 10,200 medical and psychological examinations. This included up to 200 pilot study examinations to test examination procedures and at least 10,000 examinations for the Vietnam Experience and Agent Orange Studies. The examinations were given to study participants, and individual examinations took 3 days to complete. CDC provided Lovelace with the names of veterans from those veterans that RTI interviewed. Lovelace also was required to arrange the veterans' travel to its facilities in Albuquerque, New Mexico, and to provide the veterans with lodging and meals.

Lovelace completed 5,397 examinations for which it was paid \$21.2 million. This included 147 pilot study examinations, 4,474 Vietnam Experience Study examinations, and 776 Agent Orange Validation Study examinations. Lovelace did not do any Agent Orange Study examinations because the study was cancelled.

Selected Cancers Study

CDC awarded 13 major contracts to do the Selected Cancers Study, including 8 contracts to tumor registries to identify cases of the rare types of cancer, 1 contract for the development of the control group, and 4 contracts for experts to confirm the original diagnosis of the 6 rare types of cancer. As of March 30, 1990, CDC had spent \$6 million on these contracts.

Personnel

CDC established an Agent Orange Project Office in fiscal year 1983 to manage the Agent Orange studies and staffed it with epidemiologists, statisticians, public health advisors, computer programmers, and support staff. The staff monitored the contractors' and CDC's laboratory work, analyzed data produced by the contractors, and reported on the results of the studies.

CDC spent \$15.0 million for personnel, including \$14.3 million for personnel compensation and benefits and \$650,622 for personnel travel expenses. Table I.1 shows the personnel and travel costs by fiscal year.

Table I.1: Personnel and Travel Costs

Fiscal year	Personnel compensation and benefits	Travel
1983	\$752,021	\$43,393
1984	1,887,182	77,086
1985	3,969,487	171,640
1986	2,408,419	105,752
1987	2,548,659	111,970
1988	1,803,856	96,091
1989	745,135	38,813
1990 to 3/30/90	216,389	5,877
Total	\$14,331,148	\$650,622

Equipment

CDC spent \$2.2 million on equipment for the Agent Orange studies. The most expensive item purchased was an upgrade to CDC's own computer. The Agent Orange Project was charged \$780,000 during the fourth quarter of fiscal year 1983 for its share of the upgrade, which cost CDC a total of \$1,518,342. The upgrade provided the computer with additional capacity for the Agent Orange studies. Two other expensive items purchased for the studies were a Digital Equipment Corporation VAX computer system purchased for about \$135,000 in December 1984 and a Wang Laboratories Alliance computer system purchased for about \$80,000 in September 1983. Additionally, CDC's inventory records show that CDC bought desktop computers, computer printers, computer monitors, computer modems, typewriters, calculators, dictating equipment, and office furniture.

VA's interagency agreement with CDC did not specify what would be done with the equipment after the studies were completed. However, the Agent Orange Project's deputy chief said that the items that were no longer needed on the Agent Orange studies were transferred to other CDC

offices if a need existed. If no need existed in other parts of CDC, the equipment would be disposed of in accordance with CDC's equipment disposal policy.

Miscellaneous

CDC spent \$1.1 million on miscellaneous items. The largest cost categories for these items were

- \$269,441 for printing and reproduction,
- \$247,011 for medical and dental supplies, and
- \$200,715 for telecommunications supplies.

Other miscellaneous costs included costs for transporting items, telecommunications and data transmission services, and laboratory supplies.

GAO Questionable Expenditures

Costs incurred because
contracts were awarded
prematurely.

Costs incurred because of
poor contracting and contract
administration practices.

Questionable Expenditures

We identified expenditures that we considered questionable because CDC

- awarded contracts to RTI and Lovelace before it had developed a proven methodology to identify veterans exposed to Agent Orange, and
- used other poor contracting and contract administration practices.

We found that \$6.6 of the \$33.2 million that CDC spent on contracts was for contractors' down-time and work that was not needed because CDC awarded the RTI and Lovelace contracts to do the Agent Orange Study before it knew how to identify Vietnam veterans who were exposed to Agent Orange. When RTI and Lovelace were ready to begin work on the

Agent Orange Study in 1986, CDC did not have a proven methodology to allow work to begin. We also found other examples of poor contracting and contract administration practices that increased contract costs by \$86,799.

**GAO Costs Due to Premature
Award of Contracts**

Inability to start Agent Orange Study.

Work done that was not needed for Agent Orange Validation Study.

Contractor inactivity from end of Validation Study to termination of contract.

Contract termination.

Costs Due to Premature Award of Contracts

CDC paid \$6.6 million of the \$33.2 million it spent on contracts to pay RTI and Lovelace for nonproductive time and tasks that were not required to do the studies.

The success of the Agent Orange Study hinged on CDC's ability to use military records that could accurately identify veterans who had different levels of exposure to dioxin. However, CDC awarded contracts to do the study before a proven method of identifying veterans' exposure to Agent Orange was done. As a result, CDC instructed the contractors not to begin work on the Agent Orange Study and paid the contractors \$6.6 million for nonproductive time or for work that was not needed to complete the studies. This included

- \$1.9 million that CDC paid RTI and Lovelace from January 1986 to September 1986 to remain in a state of readiness to do the Agent Orange Study interviews and examinations, based on the assumption that CDC could develop a methodology to identify veterans who had been exposed to Agent Orange;
- \$3.1 million for RTI's and Lovelace's preparation costs and Lovelace's examinations for a portion of the Agent Orange Validation Study;
- \$884,880 for Lovelace's down-time costs during a period of inactivity between the completion of its work on the Validation Study in May 1987 and the termination of its contract in October 1987; and
- \$759,190 to Lovelace for termination costs and employees' severance pay and to settle its contract.

Use of Military Records to Identify Agent Orange Exposure

Although CDC did not have a proven methodology for accurately identifying exposure to Agent Orange, it awarded contracts to RTI for \$7.5 million on August 1, 1984, and Lovelace for \$35.9 million on November 29, 1984. The contract terms did not distinguish between the work involved on the two studies and required the contractors to proceed directly from the work on the Vietnam Experience Study, which was started first, to the work on the Agent Orange Study.

The location of troops and their proximity to herbicide applications was not needed to select participants for the Vietnam Experience Study. However, the selection of the participants on the Agent Orange Study depended on a simultaneous consideration of the position of troops in Vietnam and the times and locations of herbicide applications as indicated by military records.

On November 18, 1981, in testimony before the Senate Committee on Veterans Affairs on VA's plans to use military records to identify Agent Orange exposure we said:

"While it is possible to determine that personnel were in or near sprayed areas by comparing ground troop locations with herbicide spraying missions, it is difficult to develop estimates on the nature and extent of the exposure. For example, the Army and the Marine Corps have been able to determine the proximity of companies to sprayed areas, however, the exact location of individuals assigned to these companies cannot be determined from military records. Also, companies may have reported numerous locations, only a general location, or no location on a given day. The problems encountered by the Army and the Marine Corps in gathering this information raises serious questions about the reliability of military records and the potential of the proposed feasibility study to establish individual exposure indexes."

CDC recognized the difficulties of obtaining information about Agent Orange exposure in its February 1983 Agent Orange Study protocol outline. In June 1983, OTA reviewed CDC's Agent Orange Study protocol and said that it may be impossible to study associations between health effects and Agent Orange exposure because military records would not provide meaningful exposure information. In February 1984, OTA reviewed CDC's revised Agent Orange protocol and said that a methodology for classifying veterans according to Agent Orange exposure had not been developed.

Considering the uncertainties involved with identifying Agent Orange exposure, we believe CDC should have separated the work on the Vietnam Experience Study from the Agent Orange Study by including the Agent Orange Study as a contract option. If that had been done, CDC could have declined to exercise its contract option for the Agent Orange Study if it was unable to solve the problems with identifying Agent Orange exposure. However, CDC wrote the contracts without separating the work on the two studies, because it believed that there was adequate time between the signing of these contracts in 1984 and the anticipated start of the Agent Orange Study in January 1986 to resolve the problems with the military records.

Inability to Start Agent Orange Study

During 1985, work on the Vietnam Experience Study proceeded smoothly. However, after reviewing CDC's efforts at identifying veterans with Agent Orange exposure, OTA became increasingly concerned with the methodology. On December 19, 1985, OTA wrote the appropriate congressional committees about its concerns. On January 10, 1986, the

House and Senate Committees on Veterans Affairs advised CDC that under Public Law 96-151, no new major phase of the Agent Orange Study could go forward until a protocol, including a method of exposure assessment, was approved by OTA.

On January 16, 1986, CDC ordered RTI and Lovelace not to work on the Agent Orange Study but to remain in a state of readiness for the resumption of the Agent Orange Study. This stop work order remained in effect until September 30, 1986. To compensate the contractors from January 16, 1986, to September 30, 1986, when no work was being done on the Agent Orange Study, CDC paid the contractors \$1.9 million, including \$1,359,435 to Lovelace and \$499,251 to RTI.

Work Done That Was Not Needed for Agent Orange Validation Study

During the stop work order, CDC studied whether military records could be used to accurately identify veterans who were exposed to the dioxin used in Agent Orange. CDC called this effort the Agent Orange Validation Study. CDC used a new procedure to measure the dioxin level in blood by testing the blood of 768 veterans, including 665 Vietnam veterans who, according to military records, were believed to have been exposed to Agent Orange and 103 veterans who did not serve in Vietnam. Eight veterans were unable to give a sufficient amount of blood for the blood test. A higher dioxin count in the blood of Vietnam veterans than in the blood of non-Vietnam veterans would indicate that the military records could identify exposure to Agent Orange.

CDC's plans for the Validation Study required RTI to interview participants for the study and Lovelace to take blood samples of the participants. The blood samples that Lovelace took were sent to CDC's headquarters in Atlanta, Georgia, for analysis. Additionally, CDC required Lovelace to give the 776 Validation Study participants the full medical and psychological examination that had been given on the Vietnam Experience Study. Although the examinations were not needed to do the Validation Study and were not used in the study report, CDC included them in the study because it believed that fairness dictated that the study participants be given the examinations and that this would encourage veterans to participate.

The contractors began work on the Validation Study in October 1986 and completed work in May 1987. CDC paid the contractors \$3,827,483 for the Validation Study, including \$2,044,120 for the medical and psychological examinations, \$1,038,068 for preparation costs to get ready

to do the study, \$378,203 for the interviews, and \$367,092 for the veterans' travel costs to Lovelace's facilities for the examinations and blood samples.

We found that \$3,082,188 of these costs were either directly or indirectly caused by CDC awarding the contracts before it had developed a methodology for identifying exposure to Agent Orange. This included \$1,038,068 in preparation costs for the Validation Study that would not have been incurred if CDC had developed a methodology for identifying Agent Orange exposure before it awarded the original contracts and \$2,044,120 for the medical examinations that were not needed to do the Validation Study.

Since the interviews were necessary to identify participants for the Validation Study and some amount of travel expense would have been incurred by participants in giving blood samples, we believe the \$378,203 for the interviews and the \$367,092 for the travel could be considered as necessary costs of determining whether the Agent Orange Study could be done.

Contractor Inactivity From End of Validation Study to Termination of Contract

The work on the Agent Orange Validation Study was completed in May 1987. However, the Agent Orange Study was not cancelled until October 1987. During the May to October period, CDC was evaluating the data and reaching a decision on the feasibility of the Agent Orange Study. CDC paid Lovelace \$884,880 to keep it under contract during this period of inactivity.

Contract Termination and Severance Pay Costs

CDC terminated the RTI and Lovelace contracts for the convenience of the government on October 30, 1987, because it cancelled the Agent Orange Study. As a result, CDC paid Lovelace \$759,190, including \$735,000 in termination costs and \$24,190 for severance pay for Lovelace's employees. No termination costs were paid on the RTI contract.

CDC Comments and Our Response

CDC officials commented that the contracts were not awarded prematurely by saying that at the time the original protocol was developed in 1983, CDC clearly stated that (1) many of the proposed procedures and methods were untested and that pilot study assessments were required, and (2) a recommendation not to proceed with an Agent Orange Study might be necessary. CDC's response supports our contention that, at a

minimum, the contracts should have contained option provisions for the Agent Orange Study, which CDC could have declined to exercise.

CDC officials agreed that the medical and psychological examinations were not required to do the Agent Orange Validation Study. However, the officials explained that in terms of fairness and quality of service provided to the participants, CDC felt strongly that the veterans participating in the Agent Orange Validation Study deserved the health evaluations.

GAO Poor Contracting and Contract Administration Practices

Poor contracting practices used for pilot study examinations.

Incorrect price used to calculate cost of examinations that were not done.

Personnel costs not included in the contract were paid.

Other Costs Due to Poor Contracting and Contract Administration

We found several poor contracting and contract administration practices that increased contract costs by \$86,799.

Poor Contracting Used for Pilot Study Examinations

CDC's contract with Lovelace for the medical and psychological examinations required Lovelace to do "up to 200" pilot study examinations. Lovelace proposed a fixed price of \$2,070,496 for 200 pilot study examinations, and CDC included a price of \$2,070,498 for "up to 200" examinations in the contract. The \$2 difference between Lovelace's proposal and the contract price appears to be due to the rounding of numbers.

Lovelace did 147 examinations during the pilot study and was paid the contract price, which was based on doing all 200 studies. Although Lovelace met its contractual obligation by doing "up to 200" examinations as the contract required, we believe CDC paid \$42,929 more than was necessary because the contract price included costs for the 53 examinations that were not done.

Table I.2 shows how we calculated the \$42,929 for the 53 examinations.

Table I.2: Calculation of Unnecessary Pilot Study Costs

Type of cost	Unit cost per examination	Total cost for 53 examinations
Lodging	\$134.62	\$7,134.86
Per diem	100.00	5,300.00
Payment to veterans to participate	300.00	15,900.00
Local transportation	15.34	813.02
Medical supplies	166.84	8,842.52
Subtotal	716.80	37,990.40
Fee	93.18	4,938.54
Total	\$809.98	\$42,928.94

Since the participants had to travel to Lovelace's facilities and have the examinations completed for these costs to have been incurred, we concluded that the costs were unnecessary because the examinations were not done.

We believe that these costs were unnecessarily incurred because CDC used a fixed price for the pilot study examinations as a whole and did

not negotiate an individual examination unit price. If CDC had negotiated a unit price for the individual examinations, it would have paid that unit price for each of the 147 examinations that were done.

CDC Comments

CDC officials pointed out that the contractor fulfilled its performance requirements and was paid the contract price.

Incorrect Price Used to Calculate Cost of Examinations That Were Not Done

CDC paid Lovelace \$1,359,435 for the period covering January 16, 1986, to September 30, 1986, when work was initially stopped on the Agent Orange Study. CDC negotiated this payment by concluding that Lovelace could have done 750 Agent Orange examinations during this period when work on the Agent Orange Study was stopped. CDC then negotiated a unit price of \$1,812.58 for the 750 examinations on September 30, 1986.

CDC developed the \$1,812.58 unit price by starting with a contract unit price of \$2,393.76 for the examinations and deducting \$581.18, which included costs for the payment to veterans to participate, per diem, lodging, bus service, laundry, data processing, and Lovelace's fee.

CDC paid \$22,185 more than was necessary for the 750 examinations because it used an outdated contract unit price for the examinations when it developed its unit price of \$1,812.58.

CDC changed the scope of its examinations for the 10,000 Vietnam Experience and Agent Orange examinations effective on June 3, 1985. Subsequently, on September 8, 1986, CDC negotiated a reduction in its unit price from \$2,393.76 to \$2,364.18 for the June 3, 1985, change in the scope of the examinations. Although the unit price of \$2,364.18 covered the period from January 16, 1986, to September 30, 1986, CDC used the \$2,393.76 price that was in effect before June 5, 1985, to develop its \$1,812.58 unit price. This resulted in an unnecessary payment of \$29.58 for each of the 750 examinations, or a total of \$22,185.

CDC Comments and Our Response

CDC officials disagreed with our view that the wrong price was used to negotiate the cost for the 750 examinations. CDC officials said that the \$2,364.18 negotiated unit price was based on the presumption that the full scale Agent Orange Study would be done.

Although CDC officials said that the \$2,364.18 unit price was based on the assumption that the full scale Agent Orange Study would be done, we found that CDC retroactively reduced the payment to Lovelace for its Vietnam Experience Study examinations to reflect the reduction in unit price from \$2,393.76 to \$2,364.18. Since the contract provided only one price for the Vietnam Experience Study and the Agent Orange Study examinations, we believe the \$2,364.18 unit price should have been used to calculate the price for the 750 examinations.

Payment of Personnel Costs That Were Not Included in Lovelace Contract

After Lovelace completed work on the Agent Orange Validation Study, CDC and Lovelace negotiated the payment Lovelace would receive during an inactive period from May 1987 to October 1987, when the contract was terminated. The payment included the costs for Lovelace personnel and a percentage of their salaries that could be charged by the contractor for May and June 1987.

We found that CDC overpaid Lovelace by \$21,685 for the salaries of its staff during May and June 1987. Table I.3 shows our calculation of the overpayment.

Table I.3: Calculation of Overpayment of Lovelace's Salaries

Position	Salary owed per contract	Salary paid	Amount overpaid
Medical director	\$2,593	\$7,779	\$5,186
Pathologist	2,172	10,862	8,690
Immunologist	574	2,869	2,295
Chief neuropsychologist	1,838	7,352	5,514
Totals	\$7,177	\$28,862	\$21,685

CDC Comments and Our Response

CDC officials said that its contracting office made an administrative error in not increasing the ceilings specified in the contract for personnel paid at a higher percentage. However, CDC officials said that the amount charged by the contractor for these individuals was judged necessary and appropriate by CDC's project and contracting office personnel.

We do not agree with CDC's interpretation. The contract documents clearly identified the salaries and the percentages of those salaries that should have been paid. Since there was no change in the contract amending those amounts, CDC's project and contracting offices had no legal basis to approve the higher payments.

Objectives, Scope, and Methodology

The Chairman of the Human Resources and Intergovernmental Relations Subcommittee, House Committee on Government Operations, requested that we evaluate CDC's use of funds for its Agent Orange Studies.

Our objectives were to (1) determine the amount of funds CDC received to do the studies, (2) determine how CDC used the funds it received, and (3) evaluate the contracts awarded for the studies to identify weaknesses that may have occurred in CDC's contracting and contract administration practices.

To determine the amount of funds CDC received to do the studies, we reviewed (1) the legislative history on the Agent Orange studies, (2) the interagency agreement between VA and CDC, and (3) CDC's accounting records.

To determine how CDC used the funds it received, we reviewed CDC's accounting records and supporting documents to identify the accounts it charged with expenditures for the studies. We discussed these expenditures with CDC personnel and reviewed purchase orders for the acquisition of equipment.

To evaluate CDC's contracting and contract administration practices used on the studies, we reviewed the (1) original contracts that CDC awarded and their supporting documentation and (2) modifications to the original contracts and the supporting documentation to determine the effect of each modification on the original contract. Additionally, we (1) interviewed contractor personnel and CDC's project officers and contracting officers responsible for the contracts, and (2) reviewed contractors' vouchers and CDC's payments to the contractors to determine if they were in compliance with the contract terms.

We did our review at the Department of Health and Human Services' Centers for Disease Control in Atlanta, Georgia. Our work was done from September 1989 to July 1990 in accordance with generally accepted government auditing standards.

Major Contributors to This Report

**General Government
Division, Washington,
D.C.**

William F. Engel, Assistant Director, Government Business Operations
Issues
Robert M. Antonio, Assignment Manager

**Atlanta Regional
Office**

Charles R. Chappell, Evaluator-in-Charge
Wilbur H. Crawford, Senior Evaluator